Eduardo Rodriguez, Esquire
KIM, PARDY & RODRÍGUEZ, P.A.
230 East Marks Street
Orlando, Florida 32803
Post Office Box 3747
Orlando, Florida 32802-3747
Telephone: 407-481-0066
Facsimile: 407-481-7939
Email: erodriguez@bellsouth.net
Attorneys for Plaintiff

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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

(SAN FRANCISCO DIVISION)

IN RE: BEXTRA AND CELEBREX MARKETING SALES PRACTICES AND PRODUCT LIABILITY LITIGATION	MDL No. 1699
ENID R. FARKAS, Plaintiffs, v. PFIZER, INC., PHARMACIA CORPORATION, and G.D. SEARLE LLC, (FKA G.D. SEARLE & CO.), Defendants.	Case No. C 07 2724 CRB **CIVIL COMPLAINT** **JURY TRIAL DEMANDED**

ENID R. FARKAS, Plaintiff, by and through her undersigned counsel, brings this action for damages against Defendants PFIZER, INC., PHARMACIA CORPORATION, and G.D. SEARLE LLC, (FKA G.D. SEARLE & CO.) (hereafter "Defendants") for damages arising from Defendants' design, manufacture, sale, testing, marketing, advertising, promotion, and/or distribution of the unsafe prescription anti-inflammatory drug Celebcoxib, trade name CELEBREX® ("CELEBREX").

I. PARTIES

1. Plaintiff was at all relevant times, married and adult resident citizen of the State of Florida, residing in Tamarac, Florida. (Unless otherwise specified herein, the term "Plaintiff" as used in the singular refers to, Plaintiff, Enid R. Farkas)

2. Defendant PFIZER, INC. ("PFIZER") is a Delaware corporation with its principal place of business in New York, New York. On July 16, 2002 PFIZER announced its proposed acquisition of PHARMACIA CORPORATION ('PHARMACIA"). On April 16, 2003, PFIZER completed its $60 billion acquisition of PHARMACIA. As a wholly-owned subsidiary of PFIZER, PHARMACIA acted in all aspects as PFIZER's agent and alter ego. At all relevant times, PFIZER and/or its predecessors in interest were engaged in the business of designing, testing, manufacturing, packaging, marketing, distributing, promoting, and selling the drug Celecoxib, under the trade name CELEBREX in Puerto Rico and throughout the United States.

3. Defendant G.D. SEARLE LLC, (FKA G.D. SEARLE & CO.) ("SEARLE") is a Delaware corporation with its principal place of business in Illinois. In April 2000 SEARLE was acquired by PHARMACIA, and became a wholly-owned subsidiary of PHARMACIA. At the time of PFIZER's acquisition of PHARMACIA, SEARLE was a wholly-owned subsidiary of PHARMACIA, acting as its agent and alter ego in all matters alleged in this Complaint, and is now a wholly-owned subsidiary of PFIZER. At all relevant times, SEARLE has been engaged in the business of designing, testing, manufacturing, packaging, marketing, distributing, promoting, and selling the drug Celecoxib, under the trade name CELEBREX in Puerto Rico and California and throughout the United States.

4. Defendant PHARMACIA is a Delaware corporation with its principal place of business in New Jersey. PHARMACIA was created in April 2000 through the merger of Pharmacia & Upjohn with Monsanto Company and its G.D. SEARLE unit. PHARMACIA is now a wholly-owned subsidiary of PFIZER. At all relevant times, PHARMACIA, and its predecessors in interest have been engaged in the business of designing, testing, manufacturing, packaging, marketing, distributing, promoting, and selling the drug Celecoxib, under the trade

name CELEBREX in Puerto Rico and California and throughout the United States.

5. Celecoxib was developed in 1998 by SEARLE and marketed jointly by SEARLE and PFIZER under the brand name CELEBREX. SEARLE was acquired by PHARMACIA, which was then acquired by PFIZER, in part so that PFIZER could take full control of CELEBREX.

6. At all times relevant to this action, Defendants intentionally, recklessly and/or negligently concealed, suppressed, omitted, and misrepresented the risks, dangers, defects, and disadvantages of CELEBREX, and advertised, promoted, marketed, sold and distributed CELEBREX as a safe prescription medication when, in fact, Defendants had reason to know, and did know, that CELEBREX was not safe for its intended purposes, for the patients for whom it was prescribed, and for whom it was sold; and that CELEBREX caused serious medical problems, and in certain patients, catastrophic injuries and deaths.

7. In engaging in the conduct alleged herein, each Defendant acted as the agent for each of the other Defendants, or those Defendant's predecessors in interest.

II. JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C.A. § 1332 (diversity jurisdiction). The amount in controversy exceeds $75,000.00 and there is complete diversity of citizenship between Plaintiff and Defendants.

9. Venue is proper in this District pursuant to 28 U.S.C.A. § 1391. Defendants marketed, advertised and distributed the dangerous product in this district, thereby receiving substantial financial benefit and profits from sales of the dangerous product in this district, and reside in this district under 28 U.S.C.A. § 1391(c), such that venue is proper.

10. At all relevant times herein, Defendants were in the business of designing, manufacturing, marketing, developing, testing, labeling, promoting, distributing, warranting and selling their product, CELEBREX. Defendants at all times relevant hereto designed, developed, manufactured, promoted, marketed, distributed, tested, warranted and sold in interstate commerce (including Puerto Rico and California) the aforementioned prescription drug. Defendants do

substantial business in the States of Puerto Rico and California and within this District, advertise in this district, receive substantial compensation and profits from sales of CELEBREX in this District, and made material omissions and misrepresentations and breaches of warranties in this District so as to subject them to *in personam* jurisdiction in this District. In engaging in the conduct alleged herein, each Defendant acted as the agent for each of the other Defendants or those Defendant's predecessors in interest.

III. INTERDISTRICT ASSIGNMENT

11. Assignment to the Northern District of California, San Francisco Division, is proper pursuant to MDL-1699, Pretrial Order No. 2 dated December 13, 2005, as this action is related to *In Re: Bextra and CELEBREX Marketing Sales Prac. and Pro. Liab. Lit.*, MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial Panel on Multidistrict Litigation on September 6, 2005.

IV. FACTUAL BACKGROUND

A. Facts Regarding Plaintiff

12. Plaintiff was prescribed and began taking CELEBREX daily in or about February 2001 for a period of approximately four (4) years.

13. As a direct and proximate result of using CELEBREX, Plaintiff suffered severe cardiovascular injuries. Specifically, on December 7, 2004, Plaintiff suffered myocardial infarction (heart attack), which has caused and will continue to cause Plaintiff damages and places her at risk of further serious injury or death.

14. Unaware of the risks presented by CELEBREX, Plaintiff continued to take CELEBREX until the day of her heart attack, after which time she was instructed to stop all medication, including CELEBREX.

15. Plaintiff and Plaintiff's healthcare providers were at the time of Plaintiff's heart attack and initial injury unaware—and could not have reasonably known or have learned through reasonable diligence—that such injury directly resulted from Plaintiff's ingestion of CELEBREX and Defendants' negligent and otherwise culpable acts, omissions, and

misrepresentations.

16. Plaintiff used CELEBREX in a proper and reasonably foreseeable manner and used it in a condition that was substantially the same as the condition in which it was manufactured and sold.

17. Plaintiff would not have purchased and used CELEBREX had Defendants properly disclosed the risks associated with the drug, and through diligent effort was not able to discover the risk from CELEBREX prior to her use of the drug.

B. Facts Regarding CELEBREX: Science And Other Cox-2 Inhibitors

18. CELEBREX is among a class of pain medications called non-steroidal anti-inflammatory drugs ("NSAIDs"). Aspirin, naproxed (trade name Aleve®), and ibuprofen (trade name Advil®) are examples of well-known NSAIDs.

19. NSAIDs reduce pain and inflammation by blocking the body's production of pain transmission enzymes called cyclooxygenase, COX-1 and COX-2. COX enzymes trigger the sequential oxidation of various fatty acids to create prostaglandins. Prostaglandins are important cogs in the physiology of pain, igniting hormone-like actions in the immediate vicinity of the cells that release them, thereby inducing inflammation, pain, and fever.

20. Because COX enzymes and prostaglandins increase the pain associated with tissue injury, the synthesis of prostaglandins by cells of injured tissue becomes a reasonable target for pain-management drugs.

21. Traditional NSAIDs like aspirin, ibuprofen and naproxen inhibit both COX-1 and COX-2 enzymes simultaneously, providing relief from inflammation and pain, but at the cost of potential adverse gastrointestinal effects, as the prostaglandins that are supported by COX-1 enzymes are involved in the production of gastric mucus which protects the stomach wall from the hydrochloric acid present in the stomach. By blocking the COX-1 enzyme, the body's ability to protect gastric tissue is hampered and, as a result, can cause harmful gastrointestinal side effects, including stomach ulceration and bleeding.

22. Defendants and other pharmaceutical companies set out to remedy these

gastrointestinal side effects suffered by some NSAID users by developing "selective" inhibitors, called coxibs, which targeted only COX-2 production, thus (allegedly) allowing for proper maintenance of gastric tissue while still reducing inflammation. Their development was based on the hypothesis that COX-2 was the source of prostaglandins E2 and I2, which mediate inflammation, and that COX-1 was the source of the same prostaglandins in the stomach lining. By not inhibiting COX-1, whose products provide cytoprotection in the gastric epithelium, these coxibs were thought to decrease the incidence of gastric side effects when compared to traditional NSAIDS that inhibit both COX-1 and COX-2.

23. In making this decision, however, Defendants and their predecessors in interest either intentionally ignored and/or recklessly disregarded current medical knowledge that selective COX-2 inhibition lowers prostaglandin I2 levels, the predominant COX-2 product responsible for preventing platelet aggregation and clotting, while leaving thromboxane A2, the potent COX-1 platelet aggregator and vasoconstrictor, unaffected. By selectively inhibiting prostaglandin I2 without similarly suppressing its COX-1 counterpart, CELEBREX and other coxibs expose their users to a host of clot-related cardiovascular risks, including heart attack, heart attack, and unstable angina.

24. On June 29, 1998, SEARLE and PFIZER filed for FDA approval of Celecoxib, its first major COX-2 inhibitor drug, under the trade name CELEBREX. The FDA granted preliminary approval of the new drug on December 31, 1998 for the relief of signs and symptoms of adult osteoarthritis and rheumatoid arthritis. A year later, on December 23, 1999, the FDA granted accelerated approval of CELEBREX for a second indication; the reduction of intestinal polyps as an adjunct to endoscopy and surgery in patients with familial adenomatous polyposis (FAP), a rare genetic disorder.

25. In late January 1999, following FDA approval, PFIZER publicly launched CELEBREX, their new "blockbuster" drug, in one of the largest direct-to-consumer marketing campaigns ever undertaken for prescription drugs. PFIZER's massive marketing campaign fraudulently and misleadingly depicted CELEBREX as a much safer and more effective pain

reliever than less inexpensive traditional NSAIDs. Defendants and their representatives and agents misrepresented the safety profile of CELEBREX to consumers, the medical community, healthcare providers, and third party payors.

C. Facts Regarding Celebrex's Safety And Defendants' Knowledge Thereof

26. The potential for cardiovascular risk of selective COX-2 inhibitors was known to Defendants long before the FDA granted market approval in December 1998. By 1997, and prior to the submission of the New Drug Application (the "NDA") for CELEBREX, Defendants were aware that, by selectively inhibiting only the COX-2 enzyme, CELEBREX altered the homeostatic balance between prostacylcin synthesis and thromboxane and thereby increased the prothrombotic effects of the drugs, causing blood clots to form in those who ingested it. *See* Topol, E.J., *et al.*, "*Risk of Cardiovascular Events Associated with Selective Cox-2 Inhibitors*," JAMA, August 22, 2001 at 954.

27. Pharmacologist Dr. Garrett Fitzgerald of the University of Pennsylvania reported in an editorial published in *The New England Journal of Medicine* on October 21, 2004, that contemporaneous with Defendants' launch it was known that selective COX-2 inhibitors, such as CELEBREX, suppressed the formation of prostaglandin I-2 in healthy volunteers, inhibited platelet aggregation in vitro, and may predispose patients to myocardial infarction or thrombotic heart attack. Fitzgerald, G.A., Patrono C., "*The Coxibs, Selective Inhibitors of Cyclooxygenase-2,*" N Engl J Med 2001;345:433-442.

28. Early FDA updates in March and April of 1999 similarly acknowledged this known risk, but noted, based upon PFIZER's representations, that CELEBREX "does not affect platelet aggregation (clumping), an important part of the blood clotting process." *See* FDA Updates, *"New Arthritis Drug May Have Fewer Side Effects,"* FDA Consumer March-April 1999.

29. Based on the studies performed on CELEBREX, other COX-2 inhibitors, and basic research on this type of selective inhibitor which had been widely conducted, Defendants knew when CELEBREX was being developed and tested that selective COX-2

inhibitors posed serious cardiovascular risks for anyone who took them, and presented a specific additional threat to anyone with existing heart disease or cardiovascular risk factors.

30. Despite years of studies on selective COX-2 inhibitors, as well as the disturbing new studies specifically analyzing the risks of CELEBREX, Defendants failed to take any action to protect the health and welfare of patients, opting instead to continue promoting the drug for sale even after the FDA's Drug Safety and Risk Management Advisory Committee and Arthritis Drug Advisory Committee meetings.

D. CELEBREX and Cox-2 Studies Did Not Show CELEBREX to be Safe

1. CELEBREX Long-Term Arthritis Safety Study (CLASS)

31. In September 1998, PHARMACIA sponsored an allegedly independent CELEBREX Long-Term Arthritis Safety Study ("CLASS"). The multicenter, double-blind, parallel group study sought to compare the incidence of clinically significant upper gastrointestinal events between CELEBREX 400 mg BID and Ibuprofen 800 mg. (CLASS data is found in NDA 20-998/S-009 submitted to the FDA by SEARLE on June 12, 2000. CLASS was submitted to the FDA on June 12, 2000 and reviewed by James Witter, M.D., Ph.D. (FDA Medical Officer) on September 20, 2000.)

32. On September 13, 2000, Defendants released the results of the CLASS study in the *Journal of American Medicine.* Silverstein, F.E., *et al.*, "*Gastrointestinal Toxicity with Celecoxib vs. Nonsteroidal Anti-inflammatory Drugs for Osteoarthritis and Rheumatoid Arthritis: The CLASS Study: A Randomized Controlled Trial,*" 284 JAMA 1247 (2000). Researchers enthusiastically reported a "lower incidence of symptomatic ulcers and ulcer complications combined, as well as other clinically supported toxic effects, compared with NSAIDs at standard doses."

33. Although Defendants touted the CLASS study as the primary evidence to support its theory that CELEBREX was safer for consumers who could not tolorate traditional NSAIDs in their gastrointestinal system, Defendants intentionally, recklessly and/or negligently concealed, suppressed, omitted, and misrepresented the results, risks and defects of the CLASS

study. Among other things, Defendants failed to release the study's complete twelve month results releasing only the first six months of trials, reported biased and misleading results, limited conclusions to upper gastrointestinal events despite other known risks factors, and understated known cardiovascular risks.

34. Despite Defendants' favorable CLASS Study conclusions, no other reviewing or administrative body was able to substantiate those findings. The FDA Medical Officer Review of the CLASS data found CELEBREX to be no more efficacious than other traditional NSAIDS comparators. *See generally*, FDA Medical Officer Review, NDA 20-998/S-009 submitted to the FDA by SEARLE on June 12, 2000. According to the FDA's review of the CLASS data: "Celecoxib did not demonstrate any statistical superiority to NSAIDs (pooled) or either comparator (diclofenac and ibuprofen) with regards to the primary safety endpoint of CSUGIE (Clinically Significant Upper Gastrointestinal Adverse Events) at any point in the trial although there were trends that favored celecoxib." (FDA CLASS Review).

35. The FDA Arthritis Advisory Committee similarly found no "clinically meaningful" safety advantage of CELEBREX over older NSAIDs. (FDA CDER Arthritis Advisory Committee, February 7th and 8th, 2001, Gaithersburg, Maryland). The CLASS Study failed to demonstrate a superior safety record over ibuprofen or pooled NSAID data. Based on this information, the Committee advised that further studies be done to assess the risk of COX-2 drugs and NSAIDS when taken with aspirin.

36. In a June 2002 editorial, the *British Medical Journal* chastised the Study's "misleading" and "seriously biased" nature; noting that the complete results "clearly contradict[ed] the published conclusions," and warning against the dangers of "overoptimistic," "short-term" data and "post hoc changes to the protocol." Juni, Peter, *et. at., "Are Selective COX 2 Inhibitors Superior To Traditional Non Steroidal Anti-Inflammatory Drugs?"* BMJ 2002;324:1287-1288. Most noticeably, the CLASS study considered only six months of data despite the fact that researchers at that point had 12 months of data that, when analyzed as a whole, showed no significant difference. Instead of releasing the complete 12-month results

from CLASS, PFIZER relied on and published only the first six months of data. JAMA 2000, 48:1455-1460. The results of the completed study revealed the real truth: CELEBREX offered no gastrointestinal (GI) benefit. Almost all ulcer-related complications that had occurred during the second half of the CLASS trials were in users of CELEBEX. These results clearly contradict the published CLASS conclusions.

37. Editors of the Journal of the American Medical Association (JAMA) and other medical experts were reportedly "flabbergasted" when they realized they had been "duped" by only being provided with the first six months of CLASS data. Okie S., *"Missing data on Celebrex: Full study altered picture of drug,"* Washington Post 2001 Aug 5;Sect A:11. The *Washington Post* reported JAMA editors noting: "When all of the data were considered, most of CELEBREX's apparent [GI] safety advantage disappeared."

38. Institutional bias also appeared to play a role in the Study's biased conclusions. According to the *Washington Post*, all sixteen CLASS authors were either employees of PHARMACIA or paid consultants of the company. Okie, S., *"Missing data on Celebrex: Full study altered picture of drug*," Washington Post 2001 Aug 5;Sect A:11. Moreover, at least one author, Dr. M. Michael Wolfe, a gastroenterologist from Boston University, admits he was duped by PHARMACIA. In the summer of 2000, *The Journal of the American Medical Association* asked Wolfe to participate in the "six-month" trial. Wolfe found the study, tracking 8,000 patients over a six-month period, persuasive, and penned a favorable review, which helped to drive up CELEBREX sales. It was not until early the next year, while serving on the FDA's Arthritis Advisory Committee, that Wolfe learned the study had run for one year, not six months, as the company had originally led both Wolfe and the *Journal* to believe. *Id.* Here again, when the complete data was considered, most of CELEBREX advantages disappeared.

39. Defendants also limited conclusions of the CLASS study to upper gastrointestinal events, despite other known risks factors, and understated known cardiovascular risks. A metastudy by the Cleveland Clinic published in the Journal of the American Medical Association analyzed data from two major studies, including CLASS, funded by the drug

companies and two smaller ones—all for cardiovascular risks. Debabrata Mukherjee, *et al.*, "*Risk of Cardiovascular Events Associated with Selective Cox-2 Inhibitors*," 286 JAMA 954 (2001).) The metastudy found that PHARMACIA failed to identify and study cardiovascular risks for their products. The annualized heart attack rates for patients taking Vioxx or Celebrex, the researchers found, were "significantly higher" than those in a group taking placebos. "The available data raise a cautionary flag about the risk of cardiovascular events with Cox-2 inhibitors," they concluded.

40. "A total of 36 deaths occurred during the [CLASS] study or during post study follow-up: 19 in the celecoxib group, 9 in the diclofenac group and 8 in the ibuprofen group . . . . Most deaths were cardiovascular in nature." FDA CLASS Review at 54. The increased number of adverse cardiovascular events in the CELEBREX group was not surprising, as they were also revealed in the original New Drug Application (NDA) submitted for CELEBREX. "In the original NDA, myocardial infarction was noted to occur at a higher rate in celecoxib-treated as compared to placebo treated patients. In the long term trial (Trial 024) that was included in the NDA submission, the predominate (>90%) cause of death for patients taking celecoxib at any dose was cardiovascular." FDA CLASS Review at 78.

41. Public Citizen, a public watchdog organization, also reviewed the CLASS data in its entirety. A complete review reveals the combined anginal adverse events was 1.4% in the CELEBREX group versus 1.0% in either NSAID group. Specifically, the rate of heart attack in the CELEBREX was double that of the other two NSAIDs, 0.2% vs. 0.1%, respectively.

42. Eric Topol of the Clevant Clinic reached a similar conclusion, noting that the CLASS trail MI rate was 1.6% in CELEBREX group (at a dosage of 400 mg twice a day) and 1.2% in the ibuprofen group for the 1739 patients taking low-dose aspirin. Topol noted that this numerical excess, albeit not statistically signification, was also found in the 6229 patients not taking aspirin in the trial. Eric J. Topol, *"Arthritis Medicines and Cardiovascular Events – House of Coxibs,"* JAMA 293:366. Based on this data, Topol and his colleagues concluded: "It is mandatory to conduct a trial specifically assessing cardiovascular morbidity." *Id.* Unfortunately, no such trials were ever initiated, delaying the official warnings of CELEBREX

and jeopardizing countless lives in the process.

43. The CLASS data proves that PFIZER knew that its first generation COX-2 inhibitor, CELEBREX, caused a disproportionately and statistically significant high number of adverse cardiovascular events before it was introduced to the market in January 1999. According to Public Citizen, after CLASS, the FDA recommended a trial to specifically assess the cardiovascular risks of COX-2 inhibitors. The Adenoma Prevention with Celecoxib (APC) trial was intended to be this placebo-controlled trial of CELEBREX.

2. APC Trial

44. In early 2000, the National Cancer Institute (NCI), in collaboration with SEARLE and PFIZER, initiated the Adenoma Prevention with Celecoxib (APC) trial, a randomized, double-blind, placebo-controlled study to discover the efficacy of CELEBREX in preventing the growth of pre-cancerous colon polyps. N.ENG. J. MED. 352;11 at 1072. The trial involved 2026 patients across the country with randomization to one of three groups: (1) placebo; (2) 200 mg CELEBREX twice daily; and (3) 400 mg CELEBREX twice daily. The patients, each of whom had an adenomatous polyp removed before enrollment, were followed up for a mean of 33 months while taking the study drug, with the primary objective of limiting the development of colorectal cancer.

45. On December 17, 2004, the National Cancer Institute suspended the use of CELEBREX for all participants in the APC trial due to "significant excess of cardiovascular death, myocardial infarction (MI) and heart attack." Eric J. Topol, "*Arthritis Medicines and Cardiovascular Events – House of Coxibs,*" JAMA 293:366. Analysis by an independent Data Safety Monitoring Board (DSMB) showed a two to three fold increased risk of major fatal and non-fatal cardiovascular events for participants taking the drug compared to those on a placebo with a secondary dose-response effect.

46. The absolute excess of major cardiovascular events of 13/1000 patients at the 800 mg dose (400 mg 2x day) was strikingly similar to the results of trials with rofecoxib and valdecoxib, both selective NSAID COX-2 inhibitors removed for the market for their significant

cardiovascular risks. Eric J. Topol, *"Arthritis Medicines and Cardiovascular Events – House of Coxibs,"* JAMA 293:366.

47. The FDA reported similar results, noting:

> In the National Cancer Institute's Adenoma Prevention with Celecoxib (APC) trial in patients at risk for recurrent colon polyps, a 2-3 fold increased risk of serious adverse CV events was seen for CELEBREX compared to placebo after a mean duration of treatment of 33 months. There appeared to be a dose response relationship, with a hazard ratio of 2.5 for CELEBREX 200 mg twice daily and 3.4 CELEBREX 400 mg twice daily for the composite endpoint of death from CV causes, myocardial infarction (MI), or heart attack.

April 7, 2005 FDA Alert: www.fda.gov/cder/drug/infopage/celebrex/celebrex-hcp.htm.

48. The dosage noted in the study is itself important for two reasons: first, there appears to be an association between dosage and the increase in adverse cardiovascular events; second, most patients increase dosage. PFIZER knew patients were increasing their dosages as noted in the CLASS Study: "Interestingly ... up to 70% of patients increased their dose for celecoxib." FDA CLASS Review at 74. Thus, PFIZER was aware of "dosage creep."

3. Other CELEBREX Trials

49. Several other CELEBREX trials also gave Defendants insight into the cardiovascular risks esented by CELEBREX. The Prevention of Spontaneous Adenomatous Polyps (PreSAP) trial identified the death rate from cardiovascular causes (heart attack, heart attack, heart failure, angina, or need for CV procedure) as 3.6% with CELEBREX as compared to 2.7% for placebo.

50. Public Citizen also reviewed the results of Study IQ IQ5-97-02-001 which reflected "the combined rate of all serious cardiovascular adverse events in patients getting a placebo was 2.1% but was greatly increased in those getting celecoxib to 7.7%, a 3.6 fold increase in CV risk in those people taking celecoxib. (p=0.03)." *Public Citizen*, January 26, 2005, Dr. Sidney M. Wolfe. According to Dr. Sidney Wolfe, "The study revealed a significantly increased rate (3.6-fold) of serious CV adverse events and more than a doubling in the rate of CV deaths in people using celecoxib compared to those using placebo." Id.

4. Cox-2 Studies: VIGOR and APPROVe

51. PFIZER also had access to other data which indicated a cardiovascular risk with its drugs. Specifically, PFIZER had knowledge of two studies conducted by Merck related to its Cox-2 inhibitor Vioxx – Vioxx Gastrointestinal Outcomes Research (VIGOR) and Adenomatous Polyp Prevention (APPROVe).

b. VIGOR

52. In 2000, The FDA Medical Officer Review of CLASS specifically noted the VIGOR trial and the concern over serious adverse cardiovascular events. FDA CLASS Review at 78.

53. According to VIGOR (near acronym for Vioxx Gastrointestinal Outcomes Research) Vioxx patients experienced 20% more serious clinical adverse events (statistically significant); they experienced 4.6 times more hypertension events serious enough to warrant discontinuation, 1.7 times more edema events, and 1.85 times as many congestive heart failure adverse events. By two measures of cardiovascular events related to blood clots, Vioxx had twice the risk of naproxen and the results were considered statistically significant.

54. The VIGOR study comprised the most definitive scientific evidence ever obtained about pharmaceutical products. It was a large, randomized clinical trial, the gold standard of medical research. It was a safety study with endpoints set in advance. As Merck stated many times, it was designed to provide definite proof of safety, convincing enough to silence the most skeptical critics. In medical terms, the VIGOR results raised the question of whether selective inhibition of COX-2 was a monumental mistake from the start. While the NSAID risks to the GI system were real and sometimes fatal, they were dwarfed by the cardiovascular risks of the arthritis population that needed these drugs on a daily basis. All makers of NSAIDs, including Defendants, were aware of these results.

c. APPROVe

55. Anxious to put safety questions surrounding Vioxx to rest, Merck designed another large scale trial, Adenomatous Polyp Prevention (APPROVe), which was intended to test the drug's ability to prevent or shrink colon polyps, but would also compare the cardiovascular

safety of Vioxx to a placebo control. According to the analysis conducted by Public Citizen of the APPROVe data: Vioxx "doubled the risk of any thrombotic cardiovascular event" and "doubled the risk of MI (myocardial infarction a/k/a heart attack)[1]. *Public Citizen*, January 24, 2005, at 15. Despite the available CELEBREX data and other information related to Vioxx, PFIZER never paused to reevaluate the CELEBREX data and studies.

56. The scientific data available during and after CELEBREX's approval process made clear to Defendants that their formulation of CELEBREX would cause a higher risk of blood clots, heart attack and/or myocardial infarctions among CELEBREX consumers, alerting them to the need to do additional and adequate safety studies.

57. As stated by Dr. Topol on October 21, 2004, in *The New England Journal of Medicine*, outlining Defendants' failure to have conducted the necessary trials before marketing to humans "it is mandatory to conduct a trial specifically assessing cardiovascular risk and benefit of (COX-2 inhibitors). Such a trial needed to be conducted in patients with established coronary artery disease, who frequently have coexisting osteoarthritis requiring medication and have the highest risk of further cardiovascular events."

58. Dr. Topol was also the author on the study published in August 2001 in JAMA (listed above) that reported an increased risk of thrombotic cardiovascular events in persons who used COX-2 inhibitors.

59. Based upon readily available scientific data, Defendants knew, or should have known, that their pre-approval testing of CELEBREX did not adequately represent the cross-section of individuals who were intended consumers and therefore, likely to take CELEBREX. Therefore, Defendants' testing and studies were grossly inadequate.

60. Had Defendants done adequate testing prior to approval and market launch, rather than the extremely short duration studies done on the small size patient base that was

[1] Although Merck claims that the two-fold risk of heart attacks and heart attacks seen in the APPROVe trial did not emerge until after patients had been taking the drug for 18 months, closer analysis indicates that significant increase in risk of heart attack was evident in as little as 4 months time.

actually done, the Defendants' scientific data would have revealed significant increases in incidence of heart attacks and myocardial infarctions among the intended and targeted population of CELEBREX consumers. Adequate testing would have shown that CELEBREX possessed serious side effects. Defendants should have taken appropriate measures to ensure that their defectively designed product would not be placed in the stream of commerce and/or should have provided full and proper warnings accurately and fully reflecting the scope and severity of symptoms of those side effects should have been made.

61. In fact, post-market approval data did reveal increased risks of clotting, heart attack and myocardial infarction, but Defendants intentionally suppressed this information in order for them to gain significant profits from continued CELEBREX sales.

62. Defendants' failure to conduct adequate testing and/or additional testing prior to market launch was based upon their desire to generate maximum financial gains for themselves and to gain a significant market share in the lucrative multi-billion dollar COX-2 inhibitor market.

63. At the time Defendants manufactured, advertised, and distributed CELEBREX to consumers, Defendants intentionally or recklessly ignored and/or withheld information regarding the increased risks of hypertension, heart attack and/or myocardial infarctions because Defendants knew that if such increased risks were disclosed, consumers would not purchase CELEBREX, but instead would purchase other cheaper and safer NSAIDs.

E. Facts Regarding Defendants' Marketing And Sale Of CELEBREX

64. Such an ineffective and unreasonably dangerous drug could only be widely prescribed as a result of a tremendous marketing campaign. In addition to being aggressive, the Defendants' marketing campaign was fraudulent and misleading. But for fraudulent and misleading advertising, consumers, including the Plaintiff, would not have purchased CELEBREX, a more costly prescriptive drug, ineffective for its intended purposes.

65. Defendant's marketing was so fraudulent that the FDA issued three Warning Letters to Defendants in October 1999, April 2000, and November 2000, all finding that

Defendants were unlawfully making false or misleading statements concerning the safety and/or efficacy of CELEBREX. The November letter cited two direct-to-consumer television advertisements that overstated the efficacy of CELEBREX. The FDA ordered that SEARLE immediately cease distribution of the misleading ads.

66. On February 2001, the FDA issued a Warning Letter to PHARMACIA stating that promotional activities from marketing CELEBREX were unlawful because they were "false, lacking in fair balance, or otherwise misleading." The FDA found that CELEBREX had been promoted for unapproved uses, in unapproved dosing regiments, and that the marketers had made unsupportable claims that CELEBREX was safer and more effective than other NSAIDs.

67. In August 2001, it was revealed that PHARMACIA had misrepresented the results of a post-marketing clinical study of CELEBREX when submitting it for publication. PHARMACIA selectively omitted portions of the data relating to adverse effects. The *Washington Post* reported on August 5, 2001 that, "the study had lasted a year, not six months as . . .thought. Almost all of the ulcer complications that occurred during the second have of the study were in CELEBREX users. When all of the data were considered, most of CELEBREX's apparent safety advantage[as compared to traditional NSAIDs] disappeared."

68. On January 10, 2005 the FDA again issued PFIZER a written reprimand for its promotional activities. The reprimand reads: "These five promotional pieces [3 CELEBREX and 2 Bextra] variously: omit material facts … and make misleading safety, unsubstantiated superiority, and unsubstantiated effectiveness claims." Amid continued frustration with PFIZER's continually misleading marketing strategy and ever surmounting evidence of cardiovascular dangers, the FDA Advisory Panel voted overwhelmingly that the company should never again advertise the drug [CELEBREX]."

69. At all times relevant herein, Defendants engaged in a marketing campaign with the intent that consumers would perceive CELEBREX as a safer and better drug than its other NSAIDs and, therefore, purchase CELEBREX.

70. Defendants widely and successfully marketed CELEBREX throughout the

United States by, among other things, conducting promotional campaigns that misrepresented the efficacy of CELEBREX in order to induce a widespread use and consumption. CELEBREX was represented to aid the pain and discomfort of arthritis, osteoarthritis, and related problems. Defendants made misrepresentations by means of media advertisements, and statements contained in sales literature provided to Plaintiff's prescribing physicians.

71. Despite knowledge of the dangers presented by CELEBREX, Defendants and Defendants' predecessors in interest, through their officers, directors and managing agents for the purpose of increasing sales and enhancing its profits, knowingly and deliberately failed to remedy the known defects of CELEBREX and failed to warn the public, including Plaintiff, of the serious risk of injury occasioned by the defects inherent in CELEBREX. Defendants and their officers, agents and managers intentionally proceeded with the inadequate safety testing, and then the manufacturing, sale and marketing of CELEBREX, knowing that persons would be exposed to serious potential danger, in order to advance their own pecuniary interests. Defendants' conduct was wanton and willful, and displayed a conscious disregard for the safety of the public and particularly of Plaintiff.

72. In an elaborate and sophisticated manner, Defendants aggressively marketed CELEBREX directly to consumers and medical professionals (including physicians and leading medical scholars) in order to leverage pressure on third party payors, medical care organizations, and large institutional buyers (*e.g.*, hospitals) to include CELEBREX on their formularies. Faced with the increased demand for the drug by consumers and health care professionals that resulted from Defendants' successful advertising and marketing blitz, third party payors were compelled to add CELEBREX to their formularies. Defendants' marketing campaign specifically targeted third party payors, physicians, and consumers, and was designed to convince them of both the therapeutic and economic value of CELEBREX.

73. Defendants represented that CELEBREX was similar to ibuprofen and naproxen but was superior because it lacked any of the common gastrointestinal adverse side effects associated with these and other non-steroidal anti-inflammatory drugs ("NSAIDS").

Defendants promoted CELEBREX as a safe and effective alternative that would not have the same deleterious and painful impact on the gut, but that would be just as effective, if not more so, for pain relief.

74. Yet, CELEBREX possessed dangerous and concealed or undisclosed side effects, including the increased risk of serious cardiovascular events, such as heart attacks, unstable angina, cardiac clotting, deep vein thrombosis, hypertension, and cerebrovascular events, such as heart attacks. In addition, CELEBREX, which is significantly more expensive than traditional NSAIDs[2], was actually was no more effective than traditional and less expensive NSAIDs and, just like traditional NSAIDs, carried a risk of perforations, ulcers, and gastrointestinal bleeding. Yet, Defendants chose not to warn about these risks and dangers.

75. Defendants knew of these risks before the U.S. Food and Drug Administration (the "FDA") approved CELEBREX for sale, but Defendants ignored, downplayed, suppressed, omitted, and concealed these serious safety risks and denied inefficacy in its promotion, advertising, marketing, and sale of CELEBREX. Defendants' omission, suppression, and concealment of this important information enabled CELEBREX to be sold to, and purchased, or paid for by, the Consumers at a grossly inflated price.

76. Consequently, CELEBREX captured a large market share of anti-inflammatory drugs prescribed for and used by patients. In 2004 alone, sales of CELEBREX exceeded $2 billion, despite the significantly higher cost of CELEBREX as compared to other pain relievers in the same family of drugs.

77. Because Defendants engaged in a promotional and marketing campaign that featured an advertising blitz directly targeted to consumers, that touted CELEBREX as a safer drug than other drugs in its class, while uniformly failing to disclose the health risks of CELEBREX, Defendants were able to justify pricing CELEBREX significantly higher than the cost of generic aspirin. In reality, that price inflation was not justified. Had Defendants disclosed the truth about CELEBREX, Defendants would not and could not have reaped the billions of

[2] The cost of Celebrex is at least $3-$6 per day, while an over-the-counter NSAID can cost $.50 or less per day.

dollars in CELEBREX sales that were achieved as a direct result of the concealment, omission, suppression, and obfuscation of the truth.

78. The Defendants intentionally, deliberately, knowingly, and actively concealed, omitted, suppressed, and obfuscated important and material information regarding the risks, dangers, defects, and disadvantages of CELEBREX from Plaintiff, the public, the medical community, and the regulators. This concealment and omission was deliberate, knowing, active, and uniform, was intended to induce and maximize sales and purchases of CELEBREX, and prevented Plaintiff from obtaining all the material information that would be important to her decision as a reasonable person to purchase, pay for, and/or use CELEBREX.

79. Defendants' systematic, active, knowing, deliberate, and uniform concealment, omissions, suppression, and conduct caused Plaintiff to purchase, pay for, and/or use CELEBREX; and caused Plaintiff's losses and damages as asserted herein.

80. Had Defendants done adequate testing prior to approval and "market launch," the defendants' scientific data would have revealed significant increases in heart attack and myocardial infarction amongst the intended population of CELEBREX consumers. Adequate testing would have shown that CELEBREX possessed serious side effects. Defendants should have taken appropriate measures to ensure that their defectively designed product would not be placed in the stream of commerce and/or should have provided full and proper warnings accurately and fully reflecting the scope and severity of symptoms of those side effects should have been made.

81. In fact, post-market approval data did reveal increased risks of clotting, heart attack and myocardial infarction, but Defendants intentionally suppressed this information in order for them to gain significant profits from continued CELEBREX sales.

82. Defendants' failure to conduct adequate testing and/or additional testing prior to "market launch," and active concealment and failure to warn the medical community and general public of the known cardiovascular risks of CELEBREX was particularly negligent, reckless and/or malicious given the drug's known target market. Defendants were well aware

that most patients taking CELEBREX are elderly and have higher risk of developing cardiovascular risks to begin with. Nearly half of the patients with arthritis have coexisting cardiovascular disease, and most patients, as discovered in the CLASS study, were prone to higher dosing.

83. Defendants' failure to conduct adequate testing and/or additional testing prior to "market launch" was based upon their desire to generate maximum financial gains for themselves and to gain a significant market share in the lucrative multi-billion dollar COX-2 inhibitor market.

84. At the time Defendants manufactured, advertising, and distributed CELEBREX to consumers including Plaintiff, Defendants intentionally or recklessly ignored and/or withheld information regarding the increased risks of hypertension, heart attack and/or myocardial infarctions because Defendants knew that if such increased risks were disclosed, consumers would not purchase CELEBREX, but instead would purchase other cheaper and safer NSAID drugs.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
Negligence

85. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.

86. Defendants owed Plaintiff a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling CELEBREX. This duty included the duty not to introduce a pharmaceutical drug, such as CELEBREX, into the stream of commerce that caused users to suffer from unreasonable, dangerous or untoward adverse side effects.

87. At all relevant times to this action, Defendants owed a duty to properly warn Plaintiff and the Public of the risks, dangers and adverse side effects of their pharmaceutical drug CELEBREX.

88. Defendants breached their duties by failing to exercise ordinary care in the

preparation, design, research, testing, development, manufacturing, inspection, labeling, marketing, promotion, advertising and selling of CELEBREX, including:

(a) failing to use due care in the preparation and development of CELEBREX to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

(b) failing to use due care in the design of CELEBREX to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

(c) failing to conduct adequate pre-clinical testing and research to determine the safety of CELEBREX;

(d) failing to conduct adequate post-marketing surveillance and exposure studies to determine the safety of CELEBREX;

(e) failing to completely, accurately and in a timely fashion, disclose the results of the pre-marketing testing and post-marketing surveillance and testing to Plaintiff, consumers, the medical community, and the FDA;

(f) failing to accompany CELEBREX with proper warnings regarding all possible adverse side effects associated with the use of CELEBREX;

(g) failing to use due care in the manufacture, inspection, and labeling of CELEBREX to prevent the aforementioned risk of injuries to individuals who used CELEBREX;

(h) failing to use due care in the promotion of CELEBREX to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

(i) failing to use due care in the sale and marketing of CELEBREX to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

(j) failing to use due care in the selling of CELEBREX to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

(k) failing to provide adequate and accurate training and information to the sales representatives who sold CELEBREX;

(l) failing to provide adequate and accurate training and information to healthcare providers for the appropriate use of CELEBREX; and

(m) being otherwise reckless, careless and/or negligent.

89. Despite the fact that Defendants knew or should have known that CELEBREX caused unreasonable and dangerous side effects which many users would be unable to remedy by any means, Defendants continued to promote and market CELEBREX to consumers, including Plaintiff, when safer and more effective methods of pain relief were available.

90. Defendants were, or should have been had they exercised reasonable care, in possession of evidence demonstrating that CELEBREX caused serious side effects. Nevertheless, they continued to market their products by providing false and misleading information with regard to the safety and efficacy of CELEBREX.

91. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injuries as a result of their failure to exercise ordinary care as described above.

92. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, the Plaintiff, sustained serious cardiovascular injuries; has required and will require healthcare and services; has incurred and will continue to incur medical and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the future; has suffered and will continue to suffer mental anguish, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

93. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so

as to punish Defendants and deter them from similar conduct in the future.

94. Plaintiff's spouse, MARIA MARTINEZ-GOMES, sustained a loss of consortium as a result of the injuries and damages sustained by Plaintiff incident to the use of CELEBREX. Plaintiff's spouse's damages include, but are not limited to, a loss of society, companionship, services, support, and care. All such losses are permanent and continuing in nature.

95. WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory damages, and exemplary and punitive damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

SECOND CLAIM FOR RELIEF
Strict Liability

96. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleged as follows:

97. At all times relevant to this action, Defendants were suppliers of CELEBREX, placing the drug into the stream of commerce. CELEBREX was expected to and did reach Plaintiff without substantial change in the condition in which it was manufactured and sold.

98. CELEBREX was unsafe for normal or reasonably anticipated use.

99. CELEBREX was defective in design or formulation because when it left the hands of the manufacturer and/or supplier, it was unreasonably dangerous and more dangerous than an ordinary consumer would expect. CELEBREX was also defective and unreasonably dangerous in that the foreseeable risk of injuries from CELEBREX exceeded the benefits associated with the design and/or formulation of the product.

100. CELEBREX is unreasonably dangerous: (a) in construction or composition; (b) in design; (c) because an adequate warning about the product was not provided; (d) because it does not conform to an express warranty of the manufacturer about the product .

101. CELEBREX as manufactured and supplied by Defendants was also defective due to inadequate warnings, and/or inadequate clinical trials, testing and study, and

inadequate reporting regarding the results of the clinical trials, testing and study. Defendants failed to perform adequate testing before exposing Plaintiff to the medication, testing which would have shown that CELEBREX had the potential to cause serious side effects including the injuries suffered like the Plaintiff.

102. CELEBREX as manufactured and supplied by Defendants was defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of injuries from CELEBREX, they failed to provide adequate warnings to the medical community and the consumers, to whom they were directly marketing and advertising CELEBREX; and, further, it continued to affirmatively promote CELEBREX as safe and effective.

103. CELEBREX was manufactured, distributed, tested, sold, marketed, advertised and promoted defectively by Defendants, and as a direct and proximate cause of Defendants' defective design of CELEBREX, Plaintiff used CELEBREX rather than other safer and cheaper NSAIDs. As a result, Plaintiff suffered the personal injuries described herein.

104. Information given by Defendants to the medical community and to the consumers concerning the safety and efficacy of CELEBREX, especially the information contained in the advertising and promotional materials, did not accurately reflect the potential side effects of CELEBREX.

105. Had adequate warnings and instructions been provided, Plaintiff would not have taken CELEBREX, and would not have been at risk of the harmful side effects described herein.

106. Defendants acted with conscious and deliberate disregard of the foreseeable harm caused by CELEBREX.

107. Plaintiff could not, through the exercise of reasonable care, have discovered CELEBREX's defects or perceived the dangers posed by the drug.

108. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, the Plaintiff, sustained serious cardiovascular injuries; has

required and will require healthcare and services; has incurred and will continue to incur medical and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the future; has suffered and will continue to suffer mental anguish, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

109. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory damages, and punitive and exemplary damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

THIRD CLAIM FOR RELIEF
Breach of Express Warranty

110. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.

111. Defendants expressly represented to Plaintiff and other consumers and the medical community that CELEBREX was safe and fit for its intended purposes, that it was of merchantable quality, that it did not produce any dangerous side effects, particularly any unwarned-of side effects, and that it was adequately tested.

112. These warranties came in the form of:

(a) Defendants' public written and verbal assurances of the safety and efficacy of CELEBREX;

(b) Press releases, interviews and dissemination via the media of promotional information, the sole purpose of which was to create an increased demand for CELEBREX, which failed to warn of the risk of injuries inherent to the ingestion of CELEBREX,

especially to the long-term ingestion of CELEBREX;

(c) Verbal and written assurances made by Defendants regarding CELEBREX and downplaying the risk of injuries associated with the drug;

(d) False and misleading written information, supplied by Defendants, and published in the Physician's Desk Reference on an annual basis, upon which physicians relied in prescribing CELEBREX during the period of Plaintiff's ingestion of CELEBREX, and;

(e) advertisements.

113. The documents referred to above were created by and at the direction of Defendants.

114. Defendants knew or had reason to know that CELEBREX did not conform to these express representations in that CELEBREX is neither as safe nor as effective as represented, and that CELEBREX produces serious adverse side effects.

115. CELEBREX did not and does not conform to Defendants' express representations because it is not safe, has numerous and serious side effects, including unwarned-of side effects, and causes severe and permanent injuries.

116. Plaintiff, other consumers, and the medical community relied upon Defendants' express warranties.

117. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, the Plaintiff, sustained serious cardiovascular injuries; has required and will require healthcare and services; has incurred and will continue to incur medical and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the future; has suffered and will continue to suffer mental anguish, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

118. Defendants' conduct was committed with knowing, conscious, wanton,

willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

119. WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory damages, and punitive and exemplary damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

FOURTH CLAIM FOR RELIEF
Breach of Implied Warranty

120. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.

121. Defendants manufactured, distributed, advertised, promoted, and sold CELEBREX.

122. At all relevant times, Defendants knew of the use for which CELEBREX was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

123. CELEBREX was not of merchantable quality and was not fit for its intended use, because it causes increased risk of serious cardiovascular and cerebrovasclar adverse events, including heart attacks, heart attacks and other serious and harmful adverse health effects.

124. Defendants breached the implied warranty that CELEBREX was of merchantable quality and fit for such use in violation of Md. Code Ann., Com. Law § 2-314, *et seq*.

125. Defendants were aware that consumers, including Plaintiff, would use CELEBREX for treatment of pain and inflammation and for other purposes.

126. Plaintiff and the medical community reasonably relied upon Defendants' judgment and expertise to only sell them or allow them to prescribe CELEBREX only if it was indeed of merchantable quality and safe and fit for its intended use. Consumers, including

Plaintiff, and the medical community, reasonably relied upon Defendants' implied warranty for CELEBREX.

127. CELEBREX reached consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendants.

128. Defendants breached their implied warranty to consumers, including Plaintiff; CELEBREX was not of merchantable quality or safe and fit for its intended use.

129. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, the Plaintiff, sustained serious cardiovascular injuries; has required and will require healthcare and services; has incurred and will continue to incur medical and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the future; has suffered and will continue to suffer mental anguish, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

130. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

131. WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory damages and punitive and exemplary damages together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

FIFTH CLAIM FOR RELIEF:
Fraudulent Misrepresentation & Concealment

132. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.

133. Defendants' superior knowledge and expertise, their relationship of trust

and confidence with doctors and the public, their specific knowledge regarding the risks and dangers of CELEBREX, and their intentional dissemination of promotional and marketing information about CELEBREX for the purpose of maximizing its sales, each gave rise to the affirmative duty to meaningfully disclose and provide all material information about CELEBREX's risks and harms to doctors and consumers.

134. Defendants made fraudulent affirmative misrepresentations with respect to CELEBREX in the following particulars:

(a) Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that CELEBREX had been tested and found to be safe and effective for the treatment of pain and inflammation; and

(b) Defendants represented that CELEBREX was safer than other alternative medications.

135. Defendants made affirmative misrepresentations; and fraudulently, intentionally and/or recklessly concealed material adverse information regarding the safety and effectiveness of CELEBREX.

136. Defendants made these misrepresentations and actively concealed adverse information at a time when Defendants knew or had reason to know that CELEBREX had defects and was unreasonably dangerous and was not what Defendants had represented to the medical community, the FDA and the consuming public, including Plaintiff.

137. Defendants omitted, suppressed and/or concealed material facts concerning the dangers and risk of injuries associated with the use of CELEBREX including, but not limited to, the cardiovascular, cerebrovascular, and other serious health risks. Furthermore, Defendants' purpose was willfully blind to, ignored, downplayed, avoided, and/or otherwise understated the serious nature of the risks associated with the use of CELEBREX in order to increase its sales.

138. The representations and concealment were undertaken by Defendants with an intent that doctors and patients, including Plaintiff, rely upon them.

139. Defendants' representations and concealments were undertaken with the intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to induce and encourage the sale of CELEBREX.

140. Defendants' fraudulent representations evinced their callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.

141. Plaintiff's physician and Plaintiff relied on and were induced by Defendants' misrepresentations, omissions, and/or active concealment of the dangers of CELEBREX in selecting CELEBREX treatment.

142. Plaintiff and the treating medical community did not know that the representations were false and were justified in relying upon Defendants' representations.

143. Had Plaintiff been aware of the increased risk of side effects associated with CELEBREX and the relative efficacy of CELEBREX compared with other readily available medications, Plaintiff would not have taken CELEBREX as she did.

144. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, the Plaintiff, sustained serious cardiovascular injuries; has required and will require healthcare and services; has incurred and will continue to incur medical and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the future; has suffered and will continue to suffer mental anguish, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

145. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

146. WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory damages, and punitive and exemplary damages together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

SIXTH CLAIM FOR RELIEF
(Unjust Enrichment)

147. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein.

148. At all times relevant to this action, Defendants were the manufacturers, sellers, and/or suppliers of CELEBREX.

149. Plaintiff paid for CELEBREX for the purpose of managing her pain safely and effectively.

150. Defendants have accepted payment from Plaintiff for the purchase of CELEBREX.

151. Plaintiff did not received the safe and effective pharmaceutical product for which she paid.

152. It is inequitable and unjust for Defendants to retain this money because the Plaintiff did not in fact receive the product Defendant represented CELEBREX to be.

153. WHEREFORE, Plaintiff demands judgment against Defendants and seeks equitable relief, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

SEVENTH CLAIM FOR RELIEF
(Violations of State Consumer Fraud and Deceptive Trade Practices Acts)

154. Plaintiff incorporates by reference the preceding paragraphs as if they were fully set forth herein.

155. Defendants had a statutory duty to refrain from unfair or deceptive acts or practices in the sale and promotion of CELEBREX to Plaintiff.

156. Defendants engaged in unfair, unconscionable, deceptive, fraudulent and

misleading acts or practices in violation of all Puerto Rico's consumer protection laws, identified below. Through its false, untrue and misleading promotion of CELEBREX, Defendants induced Plaintiff to purchase and/or pay for the purchase of CELEBREX. Defendants misrepresented the alleged benefits and characteristics of CELEBREX; suppressed, concealed and failed to disclose material information concerning known adverse effects of CELEBREX; misrepresented the quality of CELEBREX as compared to much lower-cost alternatives; misrepresented and advertised that CELEBREX was of a particular standard, quality or grade that it was not; misrepresented CELEBREX in such a manner that later, on disclosure of the true facts, there was a likelihood that Plaintiff would have switched from CELEBREX to another NSAID and/or chosen not to purchase and/or reimburse for purchases of CELEBREX; advertised CELEBREX with the intent not to sell it as advertised; and otherwise engaged in fraudulent and deceptive conduct.

157. Defendants' conduct created a likelihood of, and in fact caused, confusion and misunderstanding. Defendants' conduct misled, deceived and damaged Plaintiff and Defendants' fraudulent, misleading and deceptive conduct was perpetrated with an intent that Plaintiff rely on said conduct by purchasing and/or paying for purchases of CELEBREX. Moreover, Defendants knowingly took advantage of Plaintiff who was reasonably unable to protect her interests due to ignorance of the harmful adverse effects of CELEBREX. Defendants' conduct was willful, outrageous, immoral, unethical, oppressive, unscrupulous, unconscionable and substantially injurious to Plaintiff and offends the public conscience.

158. Plaintiff purchased primarily for personal, family or household purposes.

159. As a result of Defendants' violative conduct, Plaintiff purchased and/or paid for purchases of CELEBREX that were not made for resale.

160. Defendants engaged in unfair competition or deceptive acts or practices in violation of HRS § 480-2, *et seq*.

161. As a proximate result of Defendants' misrepresentations and omissions, Plaintiff and Plaintiff have suffered ascertainable losses, in an amount to be determined at trial.

162. Throughout the period described in this Complaint, Defendants repeatedly engaged in intentional misconduct characterized by trickery, deceit and a wanton, willful, conscious and reckless disregard of the health, rights and interests of the Plaintiff, and, in so conducting itself, acted with oppression, fraud, and malice toward the Plaintiff. As a result of Defendants' indifference to and reckless disregard of the health and safety of CELEBREX patients, they suffered both physical and economic harm, and all end-payors incurred economic damages. Accordingly, Defendants' conduct was highly reprehensible under controlling Supreme Court punitive damages authority, and Plaintiff is entitled to punitive and/or exemplary damages.

163. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, the Plaintiff, sustained serious cardiovascular injuries; has required and will require healthcare and services; has incurred and will continue to incur medical and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the future; has suffered and will continue to suffer mental anguish, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

164. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

165. WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory damages, and punitive and exemplary damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests the following relief:

1. General damages in excess of the jurisdictional amount of this Court;
2. Consequential damages;
3. Disgorgement of profits;
4. Restitution;
5. Punitive and exemplary damages;
6. Pre-judgment and post-judgment interest as provided by law;
7. Recovery of Plaintiff's costs including, but not limited to, discretionary Court costs of these causes, and those costs available under the law, as well as expert fees and attorneys' fees and expenses, and costs of this action; and
8. Such other and further relief as the Court deems just and proper.

Dated: May 11, 2007

KIM, PARDY & RODRIGUEZ, P.A.

Eduardo Rodriguez, Esquire
230 East Marks Street
Orlando, Florida 32803
Post Office Box 3747
Orlando, Florida 32802-3747
Telephone: 407-481-0066
Facsimile: 407-481-7939
Email: erodriguez@bellsouth.net
Attorneys for Plaintiff

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all claims so triable in this action.

Dated: May 11, 2007

KIM, PARDY & RODRIGUEZ, P.A.

Eduardo Rodriguez, Esquire
230 East Marks Street
Orlando, Florida 32803
Post Office Box 3747
Orlando, Florida 32802-3747
Telephone: 407-481-0066
Facsimile: 407-481-7939
Email: erodriguez@bellsouth.net
Attorneys for Plaintiff